sw

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/679,933	10/06/2003	Andrei Purmal	V0191.70032US00	3602

7590 02/28/2006

John R. Van Amsterdam, Ph.D.
Wolf, Greenfield & Sacks, P.C.
600 Atlantic Avenue
Boston, MA 02210

EXAMINER	
SAUCIER, SANDRA E	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 02/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	**Application No.** 10/679,933	**Applicant(s)** PURMAL ET AL.
	Examiner Sandra Saucier	**Art Unit** 1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.
2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.
3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22,26,29-33,36,37,41,45,48,63 and 64* is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5)☐ Claim(s) _____ is/are allowed.
6)☒ Claim(s) *1-22,26,29-33,36,37,41,45,48,63 and 64* is/are rejected.
7)☐ Claim(s) _____ is/are objected to.
8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.
10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a)☐ All b)☐ Some * c)☐ None of:
1.☐ Certified copies of the priority documents have been received.
2.☐ Certified copies of the priority documents have been received in Application No. _____.
3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/19/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-22, 26, 29-33, 36, 37, 41, 45, 48, 63, 64 are pending and are considered on the merits.

Information Disclosure Statement

The information disclosure statement filed 7/19/04 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. Reference B5 and B6 are missing. Applicant is advised that the date of submission of any missing element will be the date of submission for purposes of determining compliance with the requirements. See MPEP § 609C(1).

Claim Rejections - 35 USC § 112

INDEFINITE

Claims 1-22, 26, 29-33, 36, 37, 41, 45, 48, 63, 64 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 should state "A method FOR removing...". It is also unclear as to what the term "derivatives" refers. A microbicidal compound would have microbicidal activity, whether or not it is a derivative of another compound. The use of the word, derivative, is not clear. If the second recitation of "composition" in line 3, refers to the same composition as in line 2, it should be "the" composition.

Claims 7 and 8 have no antecedent basis for "treated blood product".

Claim 10 has no period. Claim 10 is indefinite because the degree of hemolysis cannot be determined. For example, if the red cells are washed in hypertonic medium, all the cells will be lysed. Therefore, any degree including 100% hemolysis fulfills the claim limitation.

Claim 18 recites "moderate mechanical stress" which is a term of comparison without a point of comparison.

Claim 10 recites "compatible with water miscible solvents" without stating what "compatible" means and the criteria for judging compatibility.

Claims 16, 18-22, 29, 30, 36 have no antecedent basis for the recitation of "the cation exchange resin **particles**".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action: A person shall be entitled to a patent unless (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent, (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 6-8, 13, 16-22, 26, 29, 30, 32, 33, 37, 41, 45, 48, 63, 64 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Khoo *et al.* [U].

The claims are directed to a process for removing a positively charged microbicidal compound from a composition comprising binding the compound to a cation exchange resin and separating the resin from the composition.

The references are relied upon as explained below.

Khoo *et al.* disclose a method of removing a positively charged microbicidal compound from a blood product composition comprising: contacting the composition with a cation-exchange resin (CM Sep-pack) and separating the compound from the composition. The compound is an antibacterial peptide, callinectin, derived from hemocytes. The compound is positively charged because it binds to a cation exchange resin, see Material and Methods, page 45, second column.

Also, Sep-Pack columns sold by Waters Millipore, are small cartridges which are eluted under low pressure developed usually by a syringe and thus have low flow rates. In any case, the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicants' column characteristics differ and, if so, to what extent from the column (Sep-Pack CM) discussed in the reference. Accordingly, it has been established that the prior art column, which have the same cationic exchange properties and share the property of being able to bind positively charged compounds, demonstrate a reasonable probability that it is either identical or sufficiently similar that whatever differences exist are not patentably significant. Therefore, the burden of establishing novelty or unobviousness by objective evidence is shifted to applicants.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action: (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-22, 26, 29, 30, 32, 33, 36, 37, 41, 45, 48, 63, 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/18969 [N] in combination with The Encyclopedia of Chemical Technology [V] and JP 04-323660 [O] or Juggi [W] or US 4,209,392 [A2].

The claims are directed to a process for removing a positively charged microbicidal compound from a composition comprising binding the compound to a cation exchange resin and separating the resin from the composition.

WO 00/18969 discloses the use of ethyleneimine oligomer which is positively charged (pages 12 and 13), to inactivate pathogens in red cell compositions (pages 14 and 15). The reference discloses that it is desirable to remove the ethyleneimine oligomer prior to transfusion of the red cells (page 15, ls. 1-3). One method suggested to remove the oligomer is washing. The reference lacks the use of a cation exchange resin to remove the oligomer.

The Encyclopedia of Chemical Technology is a generic teaching which teaches that positively charged compounds (cations) in a liquid phase are exchanged for positive or hydrogen ions on a cation exchange resins, thus removing the cationic compound from the fluid. It further teaches that there are two kinds of cationic exchange resins, weak and strong. The strong acid cation-exchange resin has sulfonic acid functional groups attached to an insoluble polymeric matrix (pages 738-739).

Juggi teaches that a cation exchange resin may be used to remove ammonium ion from blood without changing its properties. Ammonium ion is a positively charged compound.

JP 04-323660 teach that a cation exchange resin may be used to remove ammonium ion from blood without harming the properties of the blood.

US 4,209,392 teach that a strong cation exchange resin may be used to remove ammonium ion and other positively charged molecules from blood without harming the properties of the blood (Example 7).

The substitution of the step of removing the positively charged ethyleneimine oligomer using a cation exchange column instead of washing as described in the method of WO 00/18969 would have been obvious when taken with The Encyclopedia of Chemical Technology which teaches that cation exchange resins can be used to remove positively charged compounds from fluids. Further, Jiggi or JP 04-323660 or US 4,209,392 show that cation exchange resins have been used in blood composition in the past to remove positively charged molecules and that the properties of the blood are not compromised by such treatment.

The addition of the step of using a cation exchanger to remove a positively charged compound such as an ethyleneimine oligomer from a blood composition in the method of WO 00/18969 would have been obvious because WO 00/18969 teaches that it is desirable to remove the oligomer prior to transfusion. Both the step of using a cation exchange resin and the washing step are known methods of removing positively charged molecules from blood compositions. Therefore, it would be obvious to use either or both of these methods to remove a positively charged ethyleneimine oligomer from a blood composition. The order of performance of the steps may be reversed in the absence of evidence of criticality of the order.

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/18969 [N] in combination with The Encyclopedia of Chemical Technology [V] and JP 04-323660 [O] or Jiggi [W] or US 4,209,392 [A2] as applied to the claims above, and further in view of DOWEX Ion Exchange Resins [X].

The claims are further directed to the use of the specific cation exchanger, DOWEX 50WX8.

Dowex 50WX8 [X] is a commercially available cation exchange resin as evidenced by the catalog downloaded from the Dowex online site. It is considered that the substitution of one known cation exchange resin for another known cation exchange resin such as Dowex 50WX8 is obvious in the absence of evidence to the contrary. Evidence that Dowex 50WX8 is superior in this application to other types of cation exchange resins will be carefully considered.

One of ordinary skill in the art would have been motivated at the time of invention to make these substitutions or additions in order to obtain the results as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Conclusion

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to the office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (571) 272-0922. The examiner can normally be reached on Monday, Tuesday, Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sandra Saucier
Primary Examiner
Art Unit 1651
February 16, 2006